

Supporting Statement for an Information Collection Request (ICR) Addendum Under the Paperwork Reduction Act (PRA)

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1. EXECUTIVE SUMMARY

1(a). Identification of the Information Collection – Title and Numbers

Title: Partial Update of the TSCA Section 8(a) Inventory Data Base, Production and Site Reports (Chemical Data Reporting)

ICR Numbers: EPA ICR No.: 1884.13 OMB Control No.: 2070-0162

EPA Form Numbers: EPA Form U EPA 7740-8

Docket ID Number: EPA-HQ-OPPT-2013-0721

1(b). Docket Information

The information collection request (ICR) that explains the information collection activities and related burden and cost estimates, as well as other supporting documents related to the ICR, are available in the docket established for this ICR. The docket can be viewed online at <http://www.regulations.gov> or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

1(c). ICR Status

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid control number issued by the Office of Management and Budget (OMB). The OMB control numbers are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

This is an addendum to an existing ICR (EPA ICR No. 1884.12; OMB Control No. 2070-0162; entitled “[*Information Collection Request for*] Chemical Data Reporting under the Toxic Substances Control Act (TSCA section 8(a))”; approved through June 30, 2023). This addendum is located in docket number EPA-HQ-OPPT-2018-0321.

1(d). Abstract

This ICR addendum addresses the paperwork requirements in a final rule (RIN 2070-AK57) that amends the information collection activities of the CDR program (40 CFR Part 711). An economic analysis (EA) provides estimations of the burden and costs associated with the final changes to the TSCA Section 8(a) Small Manufacturer Definition (SMD)/size standards.

The CDR data collection provides chemical manufacture, processing, and use information that helps EPA identify what chemicals, from those listed on the TSCA Inventory¹, the public may be exposed to as consumers or in commercial and industrial settings. The data also help EPA assess routes of potential exposure to those chemicals.

¹ The TSCA Inventory is a listing of chemical substances manufactured, imported, and processed for commercial purposes in the United States.

EPA has used the CDR rule to collect basic manufacturing information for selected chemical substances on the TSCA Inventory eight times beginning in 1986. More recent collections, beginning in 2006, included additional information relating to the manufacture, processing, and use of those chemical substances. The CDR data collection is on a four-year reporting cycle and contains detailed manufacturing and processing information drawn from the principal reporting year; the rule also contains basic information on production volume, by year, for the three years prior to the principal reporting year. For example, for the 2020 reporting cycle, the principal reporting year is 2019; the three years prior are 2016, 2017 and 2018.

As finalized, the 2020 and future CDR submissions include an updated definition of small manufacturers, including a new definition for small governments. Note that these definitions apply to all rulemakings promulgated under section 8(a) of the Toxic Substances Control Act (TSCA), including CDR.

In addition to CDR, there are five chemical-specific rules that refer to the current TSCA section 8(a) small manufacturer definition listed in 40 CFR 704.3 and therefore would be impacted by the proposed approach for updating the standards. These impacted five rules are: §§ 704.25 (11-Aminoundecanoic acid); 704.33 (P-tert-butylbenzoic acid (P-TBBA), p-tert-butyltoluene (P-TBT) and p-tert-butylbenzaldehyde (P-TBB)); 704.45 (Chlorinated terphenyl); 704.95 (Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis- (EDTMPA) and its salts); and 704.175 (4,4'-methylenebis(2-chloroaniline) (MBOCA)). There is no measurable impact to these other TSCA section 8(a) rules because EPA has not received any chemical reports for the rule for an extended period of time.

Legal authority: Under TSCA section 8(a) (15 USC 2607), the Environmental Protection Agency (EPA) is authorized to collect certain information on chemical substances manufactured (including imported) or processed in the United States. In addition, under TSCA section 8(b), the Agency is required to compile and keep current, via periodic inquiry, the Inventory of Chemical Substances in Commerce (TSCA Inventory). More details are provided in Unit 2(a) of this Supporting Statement.

Respondents/affected entities: Entities potentially affected by this ICR include companies manufacturing (including importing) chemical substances listed on the TSCA Inventory and regulated under the TSCA section 8(a) CDR Regulation.

Respondent's obligation to respond: Respondents are obligated to report to EPA.

Confidentiality of responses: Confidentiality claims limit access to the CDR data, especially by the public. EPA recognizes that some information submitted to the Agency is legitimately confidential. Because of this, EPA's review of confidential data is an inherently governmental function that EPA must perform to protect human health and the environment.

Estimated total number of potential respondents: 5,660.

Frequency of response: The collection occurs every four years. The next CDR collection will occur in 2020.

Estimated total annual burden: -23,014 hours. Burden is defined at 5 CFR 1320.3(b).

Estimated total annual costs: -\$1,760,578, includes no annualized capital investment or operational and maintenance costs.

Changes in the estimates: There is an overall annual decrease of 23,014 hours in the total respondent burden that is currently approved by OMB for this ICR. This decrease reflects updates to the definition of small manufacturers and a new definition for small governments. Further details about these changes are included in this ICR supporting statement.

2. NECESSITY OF THE INFORMATION COLLECTION

2(a). Related Legal and/or Administrative Requirements

In 1984, EPA finalized a rulemaking, required under TSCA section 8(a)(3)(B), establishing standards that define small manufacturers for section 8(a) reporting purposes (49 FR 45425). Manufacturers meeting these standards were generally exempt from section 8(a) recordkeeping and reporting requirements. A small manufacturer was defined in 40 CFR 704.3. This definition can be summarized as:

- First standard (dual-prong \$40 million and 100,000 pounds (lb)): A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lb), the manufacturer or importer will not qualify as small for the purposes of reporting on the production of that substance at that site, unless the manufacturer or importer qualifies as small under the second standard below.
- Second standard (very small, single-prong \$4 million): A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of the substances produced or imported by that manufacturer or importer.
- Inflation index: EPA shall make use of the Producer Price Index (PPI) for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the PPI for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide Federal Register notification when changing the total annual sales values.

At the time of the 1984 rulemaking, the CDR rule was not yet established, and the landscape of TSCA section 8(a) rules was different than it is today. No monitoring information collection was in place, and EPA's small manufacturer definition was based on an ad hoc compilation of industry data. In analysis of the structure of the definition, the more restrictive two-prong standard was found to be more effective in targeting the exemption to small manufacturers than a single-prong standard (even if the two prongs were used in parallel). That two-pronged standard included parent company revenue and site-level production. Additionally, total employment was found not to be a good substitute for annual sales revenue as an indicator of firms' abilities to absorb reporting costs (ICF, 1982).² In setting the levels for standards, EPA

² Note that SBA also found that its initial employment-based size standard at 500 employees adopted at its inception in 1953 was not necessarily the best way to capture the size of businesses in industries outside of

weighed whether to maximize the number of chemicals reported, chemical reports received, production volume reported upon, or the number of sites reporting. EPA ultimately chose an approach designed to maximize the number of sites reporting in order to obtain information that is representative of firms of different sizes. The structure of the TSCA definition implemented in 1984 used annual sales revenue and production volume levels set for desired coverage; information losses were expected to be at 10 percent of chemicals, 36 percent of companies, 12 percent of sites, and 15 percent of chemical reports (See 49 FR 45425-45431).

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) was signed into law, amending TSCA. In addition to numerous other requirements outside the scope of this analysis, the new law included a requirement for EPA to consult with SBA, review the adequacy of the existing section 8(a) definition, including size standards. Pursuant to TSCA section 8(a)(3)(C), on November 30, 2017, EPA determined that revision of the size standards is warranted (82 FR 56824). In the determination, EPA first reviewed the change in the PPI for Chemicals and Allied Products between 1988 (the year the general size standards at 40 CFR 704.3 were last revised) and 2015 (the most recent year of PPI data available at that time) and found a 129% change. This level far exceeds the “20 percent inflation index specified as a level above which EPA may adjust annual sales levels in the current standard if deemed necessary” (82 FR 56824). EPA also took into consideration the comparison of this result to small manufacturer revenue size standards under the existing SBA small business definition. After additional consultation with SBA, and review of public comments, EPA made the final determination that revision of the standards is warranted and is updating the section 8(a) small manufacturer definition. For the TSCA section 8(a) small manufacturer definition update, EPA is finalizing an update to the current definition based on inflation by adjusting the sales standard level for the first part from \$40 million to \$120 million and for the second part from \$4 million to \$12 million.

2(b). Necessity of the Information Collection

The CDR data collection is necessary to provide chemical manufacture, processing, and use information that helps EPA identify what chemicals the public may be exposed to as consumers or in commercial and industrial settings. The data are also necessary to help EPA assess routes of potential exposure to those chemicals.

2(c). Uses, Users, and Purpose of the Information Collection

EPA’s OPPT, other EPA Offices and/or other Federal agencies will generally be the primary groups for which information will be collected. However, to the extent that reported information is not considered to be CBI, environmental groups, environmental justice advocates, state and local government entities and other members of the public may access this information for their own use.

manufacturing, and consequently also developed a revenue-based standard, later going on to expand the number of size standards—setting them at different levels according to NAICS codes (SBA, 2009). In a recent update to this methodology, SBA states, “SBA generally prefers receipts as a measure of business size because it measures the value of total output of a business concern and can be easily verified using business tax returns and financial records. The Small Business Act provides that the size of manufacturing firms be based on the number of employees and size of services firms based on average annual receipts. Accordingly, SBA primarily uses the number of employees for manufacturing industries and average annual receipts for services industries.” (SBA, 2019; pp. 9-10). Note also that the TSCA regulated universe defines manufacturers to include importers, whereas SBA’s regulated universe pertains only to domestic manufacturers.

The reporting methods, including the reporting tool and electronic registration, help to ensure that the information reported to EPA is accurate and in compliance with the CDR requirements. In addition, the data elements reported have practical utility for users of the data within EPA and for the public. For more information on CDR reporting methods, see Section 2(b) of the 2018 CDR ICR Renewal (EPA, 2018b).

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non-Duplication

The data included in this information collection addendum (i.e., production volume, chemical manufacture, exposure, and processing and use data) are not collected comprehensively or systematically at the national level by any other entities.

3(b). Consultations and Public Comments

4. During the public comment period for the proposed rule from April 24, 2019, to June 24, 2019, EPA received 10 comments on the small manufacture definition as it relates to the reporting and recordkeeping burden associated with reporting to CDR.

Some commenters supported the proposed update to the current two-standard definition at 40 CFR 704.3 while other commenters requested that EPA implement a variable employment-based size standard for CDR and TSCA section 8(a) that uses different industry specific standards defined by NAICS codes, similar to the TSCA fees rule which is based on the SBA definition for small business, as opposed to the current two-standard revenue-based definition. Many commenters did not believe that the proposed update provided enough additional regulatory relief. EPA considered several approaches including approaches by SBA and others to establishing a small manufacturer definition. After considering multiple options, EPA determined that the proposed option properly updated the current definition and provided additional burden reduction while minimizing the loss of information to the Agency. Disproportionate losses of reporting on TSCA Work Plan chemicals constitute a potential loss of information necessary for key Agency decisions.

For a more detailed discussion of the response to comments associated with paperwork burden please see Attachment C.

4(a). Effects of Less Frequent Collection

If data were collected less frequently there would be a significant loss of data to the agency and general public as there are no alternative data sets as comprehensive as CDR for the chemical manufacturing industry. Requiring this data collection every four years will help to increase the agency's ability to understand the chemical industry and monitor the production levels of chemical substances manufactured (including imported) in the United States. As chemical industry product lines and manufacturing in the United States change substantially from one submission period to the next, more current information enhances the agency's ability to make more accurate chemical substance risk assessment and management decisions in a timely and cost effective manner.

4(b). Small Entity Flexibility

EPA is updating the TSCA section 8(a) small manufacturer definition, as required, based on the determination made on November 30, 2017 (82 FR 56824). The final definition applies to small manufacturers for TSCA section 8(a) rules, including CDR, unless a different standard is identified in the regulatory text of a particular rule. Small manufacturers (including importers), in accordance with TSCA section 8(a) and 40 CFR sections 711.9, are generally exempt and therefore are generally not subject to any of the reporting or recordkeeping requirements.

The final definition for small manufacturers updates the current two-standard definition at 40 CFR 704.3 by adjusting the sales figure for the first standard from \$40 million to \$120 million (while retaining the same production volume level at 100,000 lb) and adjusting the sales figure for the second standard from \$4 million to \$12 million (applies to any production volume).

In addition to the updated standards for small manufacturers, EPA is establishing a size standard for small governments. Currently, there is no small government definition in TSCA section 8(a). This definition will reduce the reporting burden for governments considered small manufacturers under TSCA. EPA will use the same definition for small governments as the Regulatory Flexibility Act (5 U.S.C. section 601(5)), which is: A small governmental jurisdiction is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. States and tribal governments are not considered small governments.

Appendix D contains relevant excerpts from the 2020 CDR Instructions for Reporting.

4(c). General PRA Related Guidelines

This collection does not exceed any of the Paperwork Reduction Act (PRA) guidelines at 5 CFR 1320.6, with the exceptions listed below.

5. The record retention period of this collection is five years, as specified in 40 CFR 711.25, exceeding the PRA maximum of three years. EPA is not finalizing changes to the record retention period.

5(a). Confidentiality

Confidential business information (CBI) claims limit public access to the CDR data. EPA recognizes that some information submitted to the Agency is legitimately confidential business information, and EPA reviews CBI data in its mission to protect human health and the environment, in accordance with TSCA section 14(f) and (g). The 8(a) SMD Update Rule does not make any changes to how or what submitters claim as CBI. A separate rulemaking, titled "Economic Analysis for the Final Rule on TSCA Chemical Data Reporting (CDR) Revisions" (EPA, 2019a) handles the changes to confidentiality claims effected by the Lautenberg Act.

5(b). Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

6. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a). Agency Activities

The Agency develops and maintains the electronic tool used to collect and verify data and routinely conducts other activities related to the processing, analysis and storage of the information collected under this rule. In this ICR Addendum, only the Agency activities related to the changes created by the final rule are considered including:

- Submission receipt and tracking
- Data Review
- Quality Control³

6(a). Estimated Agency Costs

The Agency engages in several activities related to CDR reporting, including: document receipt and tracking; quality control of data, including protection of CBI; backup systems operation; data processing; systems development; contract oversight and management; publication of materials and creating PDFs of forms; and operation of the TSCA Hotline to handle CDR-related calls. For the 8(a) SMD Update, EPA estimates over the four-year reporting cycle incremental Agency burden reduction and cost savings at 14 hours and \$1,816 due to a reduction in the number of sites and chemical reports resulting from the change in the small manufacturer definition. See Appendix A for a detailed derivation of Agency costs.

6(a)(i). Collection Schedule

EPA is not making any changes to the collection schedule. The submission period/schedule follows the requirements of 40 CFR 711.20. The submission period for the next collection in 2020 will be from June 1, 2020 to September 30, 2020.

Activity	Timeline
Public outreach efforts: articles in industry press, meetings with regulated community, and information on the CDR website	2018-2020
Email to 2020 CDR e-mailing list and other stakeholders with instructions for obtaining the reporting form and initiating reporting	Early 2020
Open period for submitting 2020 CDR Forms	June 1, 2020 to September 30, 2020

Use of Technology to Facilitate Collection Activities: Submitters are required to submit information associated with this data collection electronically via the Internet using e-CDRweb and CDX.

EPA notifies potential submitters of the need to report in three ways: (1) makes available guidance describing CDR reporting requirements at chemical industry conferences and meetings, and through web and listserv announcements, (2) sends email notices to previous CDR submitters, and (3) publishes articles in the trade press. The requirement to report is

³ Quality control activities performed by program staff involve comparative analysis of the data received to identify if there are any unexpected anomalies or inconsistencies of the data, such as between sites with the same parent companies, followed by outreach to the reporting companies to obtain corrections or confirmation that reported information is correct.

based on the CDR regulations; potential submitters that do not receive a notification as listed above or who do not read published articles are still required to report. Reporting materials, including a non-submission version of the Form U and a variety of instructions documents (Instruction Manual, Q&As, Case Studies, Fact Sheets), are available on EPA's CDR website. Submitters can also obtain these materials from the TSCA Hotline. Submitters obtain the e-CDRweb reporting tool (which enables the completion of the Form U for submission) as part of the CDX electronic web-based registration process. The e-CDRweb reporting tool enables the user to complete Form U for submission to EPA.

EPA receives all CDR submissions electronically. The CDX registration process, required for all submitters, provides a user ID, which the submitter uses to access e-CDRweb.

Information quality control and validation begins with the e-CDRweb reporting tool, which is programmed to help the submitter provide the information required, in the correct format, as required by the CDR rule.

To aid persons subject to this information collection, the Agency's TSCA and CDX Hotlines are available to answer questions regarding the CDR requirements or submission process. When Hotline staff is unable to answer questions, the submitter is referred to OPPT's Information Management Division (IMD) or Chemical Control Division (CCD), as appropriate. Submitters can also email their questions to the e-CDRweb mail site at eCDRweb@epa.gov. Other Divisions within OPPT or the Office of Environmental Information (OEI) may respond as necessary.

7. THE RESPONDENTS AND INFORMATION COLLECTION (IC) ACTIVITIES

For each respondent category, this section of the ICR describes the respondents, the information collection activities and related estimates of burden and costs associated with those activities.

For the 2020 reporting cycle (as previously in the 2016 reporting cycle), manufacturers (including importers), must submit a Form U for each site at which 25,000 pounds or more (or 2,500 pounds or more, if applicable⁴) was manufactured (including imported) for a chemical substance in *any* calendar year in the principal reporting year and the previous three years. Estimates are presented according to the full reporting cycle first (Table 5 -1 through Table 5 -5) and then converted to a basis used for the ICR period (Table 6-1).⁵ Burden estimates are derived consistent with estimates described in the ICR renewal (EPA, 2018b) and the Economic Analysis for the 8(a) SMD Update Rule (EPA, 2019b).⁶

⁴The reporting threshold is lower (2,500 lb) for chemical substances that are the subject of certain TSCA actions (see 40 CFR 711.8(b)), including:

- A rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6;
- An order issued under TSCA sections 5(e) or 5(f); or
- Relief that has been granted under a civil action under TSCA sections 5 or 7.

⁵Note that some results in this analysis are presented on a one-year basis. The annual estimates are simply the four-year estimates divided by four. EPA acknowledges that activities may be spread unevenly across the four years. However, for purposes of burden and cost tracking, a constant annual burden and cost is a useful standardized metric for this and other analyses.

⁶The economic analysis defines its baseline as the predicted 2020 CDR conditions using the 2016 CDR (EPA, 2018a). The 2016 CDR is considered an appropriate baseline data source without adjustment for two reasons: (1) in the history of CDR development, the information from the 2016 CDR is the most complete, covering a

The 8(a) SMD Update Rule involves changes that involve removal of reporting requirements for a portion of chemicals at a site, and changes that involve removal of reporting requirements for an entire site. See Section 5.3 of EPA (2019b) for more details.

7(a). Methodology for Estimating Respondent Burden and Costs

The regulated community consists of companies manufacturing (including importing) chemical substances listed on the TSCA Inventory and regulated under TSCA section 8(a). In general, the industry segments that compose the regulated community for the rule are those that produce or import chemical substances. Most respondents expected to be subject to this ICR have previously reported CDR information. The Agency's previous experience with CDR collections has shown that the majority of the respondents affected by this collection activity are from the following NAICS code categories:

- 325 - Chemical Manufacturing
- 324 - Petroleum and Coal Product Manufacturing

In addition to the anticipated respondents from the NAICS listed above, the regulated community consists of manufacturers of byproducts that are required to report under certain TSCA section 8(a) rules, including CDR. Byproduct manufacturers may be listed under a different primary activity for a site, such as NAICS codes 22, 322, 327310, 331, and 3344 (namely utilities, paper manufacturing, cement manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing, respectively). The subsectors identified above represent the designation of sites that likely would be subject to CDR reporting. However, this list does not include all potentially affected entities. Other types of entities not listed in this unit could also be subject to reporting.

As noted above, in November 2017 EPA published a determination that the small manufacturer definition needs to be updated (82 FR 56824 November 30, 2017). EPA is finalizing an update to this standard⁷ and is establishing a section 8(a) definition for small government entities.

5(a)(i) Respondent Activities

For the analysis in this section, the respondent is defined as a manufacturing site, which could include a government site. There is one response per respondent, as one Form U per site accommodates multiple chemical reports in the same submission. Incremental activities associated with preparing and submitting a Form U in response to the rule include rule familiarization, compliance determination, and form completion. The rule does not change any recordkeeping requirements, and therefore no associated burden and cost estimates for this activity are included in this analysis. Last, for reporters not already registered in CDX, individuals must complete CDX registration, including e-signature. The rule does not change any requirements for CDX activities, and therefore no associated burden/cost estimates for this activity are included in this analysis. General descriptions of changes to activities are as follows:

- **Rule Familiarization increase due to increased regulatory complexity:** The final

comparable four-year period; and (2) upon review of year-to-year counts for chemicals, sites, and chemical reports there is high variance from year to year without a noteworthy trend upward or downward in counts.

⁷ These standards apply to all TSCA section 8(a) rules, including CDR, unless a different standard is identified in the regulatory text of a particular rule.

rule revises the general TSCA section 8(a) small manufacturer definition. Reporters must familiarize themselves with the new requirements. This activity entails reading the rule, understanding the reporting and administrative requirements, and determining what tasks are required in order to meet reporting requirements. In future cycles, only new reporters will incur incremental increases to rule familiarization.

- **Compliance Determination increase due to increased regulatory complexity:** Under the final TSCA section 8(a) small manufacturer definition, incremental compliance determination is considered negligible for industry reporters because the final definition retains the same structure as the current definitions with adjustments only to the levels of the two revenue standards. Incremental compliance determination is, however, estimated for government reporters under the TSCA section 8(a) small government definition because there is no existing definition for these entities. Note that, by convention, new reporters and experienced reporters are assumed to incur the same levels of compliance determination.
- **Form Completion:** The final rule does not alter the activities required of reporters. Rather, it affects whether, and for which chemicals, these sites are required to report. As such, the final small manufacturer definition and the new small government definition result in decreases in sites and chemical reports.

7(b). Estimating Respondent Burden and Costs

This section presents the relevant unit burdens and costs of the information collection activities to respondents in terms of the time required by reporters to perform the activities as outlined in the introductory section of this document.

5(b)(i) IC#1 TSCA Section 8(a) SMD Update

Incremental experienced reporter unit burden for respondent activities associated with the rule is presented in Table 5 -1. Unit burdens in this table reflect changes in activities that are applied universally to all reporters. The activity-level unit burden estimates for changes in Table 5 -1 are based on estimates for similar activities and best professional judgment (for more detail, see EPA (2019b)).

Table 5-1: Incremental Activity-Level Unit Burden per Four-Year Reporting Cycle, Experienced Reporters

Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity-Level Unit Burden (hours)	Proportion of Affected Sites/Chemical Reports	Adjusted Unit Burden per Site/Chemical Report
Small Manufacturer and Small Government Definitions							
Rule Familiarization increase due to increase regulatory complexity (Industry and Gov't)	Site	0.000	0.000	0.000	0.000	0.000	0.000
Compliance Determination increase due to increase regulatory complexity (Industry)	Site	0.000	0.000	0.000	0.000	1.000	0.000
Compliance Determination increase due to increase regulatory complexity (Gov't)	Site	0.052	0.118	0.000	0.170	1.000	0.170
General Note:							
• For details on development and assumptions associated with items in this table, see 8(a) SMD Update EA (EPA, 2019b).							

Incremental new reporter unit burden for activities associated with the 8(a) SMD Update is presented in Table 5-2. These unit burdens are applied to new reporters under future cycle conditions for the final rule.

Table 5-2: 8(a) Incremental Burden, Experienced and New Reporters, Four-Year Cycle Industry and Government

Activity	Experienced Reporters	New Reporters	Overall ¹
	Unit Burden per Average Site (Hours)	Unit Burden per Average Site (Hours)	Unit Burden per Average Site (Hours)
Industry			
Rule Familiarization ²	0.000	1.730	0.256
Compliance Determination ³	0.000	0.000	0.000
Recordkeeping	0.000	0.000	0.000
Average Multi-Chemical Form Completion	0.000	0.000	0.000
8(a) SMD Total	0.000	1.730	0.256
Government			
Rule Familiarization ⁴	0.000	0.000	0.000
Compliance Determination ^{3,5}	0.170	0.170	0.170
Recordkeeping	0.000	0.000	0.000
Average Multi-Chemical Form Completion	0.000	0.000	0.000
8(a) SGD Total	0.170	0.170	0.170
General Notes:			
• For details on development and assumptions associated with items in this table, see 8(a) SMD Update EA (EPA, 2019b).			
• There may be entities that incur burden from rule familiarization (if new to CDR) and compliance determination but that are not required to send a CDR submission. For purposes of this analysis, such effects are neglected per the convention used in EPA (2018b).			
Footnote:			
¹	As in the analysis in Table 5-9 of EPA (2019b), overall unit burden is based on 14.82% new reporting sites. The exception is government entities, which are assumed to have 100% experienced sites.		
²	The estimate for industry new reporter incremental Rule Familiarization burden consists of 0.505 hours of Managerial labor and 1.225 hours of Technical labor (see EPA (2019b) for justification).		
³	Compliance Determination for industry new reporters is estimated at the same levels as for experienced reporters.		

- ⁴ The estimate for government new reporter incremental Rule Familiarization burden is zero because all governments are assumed to be experienced.
- ⁵ Compliance Determination for government reporters consists of 0.052 hours of Managerial labor and 0.118 hours of Technical labor (see EPA (2019b) for justification).

Unit costs are derived by combining relevant wage information with unit burden estimates. See Appendix B for information on the industry wage rates used in this analysis. Unit reporter burden and reporter cost per site for the SMD Update are presented in Table 5-3. EPA estimates incremental reporter burden and cost at approximately 15 minutes and \$20 per industry site and approximately ten minutes and \$13 per government site per four-year reporting cycle.

Table 5-3: Incremental Unit Burden and Cost per Site, Four-Year Cycle, Experienced and New Reporters, Industry and Government

	Overall average burden per site (hours)	Overall average cost per site (2018\$)
Universal Changes		
Industry		
8(a) SMD incremental rule familiarization and compliance determination	0.256	\$19.67
Industry Total	0.256	\$19.67
Government		
8(a) SGD incremental rule familiarization and compliance determination	0.170	\$13.05
Government Total	0.170	\$13.05

5.(c). Respondent Universe, Total, and Bottom Line Burden Hours and Costs

5(c)(i) IC#1 TSCA Section 8(a) SMD Update

Table 5-4 presents the change in numbers of sites and chemical reports due to the rule (EPA, 2019b). Note that in the following calculation, all sites in the baseline are also additionally affected by incremental rule familiarization and compliance determination for the rule.

Table 5-4: Change in Sites and Chemical Reports

Regulatory Provision Description	Change in Number of Sites	Change in Number of Chemical Reports	Change in Number of Full Chemical Reports ¹
8(a) SMD Update	-127	-1,248	-1,173
8(a) SGD	-4	-6	-5
Overall	-131	-1,254	-1,178
Footnote: ¹ Full Chemical Report counts are used later in this analysis to calculate incremental Agency burden.			

Total Reporter Burden/Cost. Estimates of the reporting burden and cost per four-year reporting cycle are shown in Table 5-5. Total burden and cost are calculated for changes to reporting activities by multiplying the unit burdens and costs in Table 5-3 by the respective number of reporting sites. Total burden and cost attributable to reporting universe changes (reductions) are calculated for relevant sites and chemical reports using baseline information (for more detail, see EPA (2019b)).

Table 5-5: TSCA Section 8(a) SMD Update Incremental Reporting Burden and Cost for Four-Year Reporting Cycle, New and Experienced Reporters

	Baseline Number of Sites	Number of Sites Under Final Rule	Future Cycles			
			Unit Burden (hours)	Unit Cost (2018\$)	Burden (hours)	Cost (2018\$)
Changes to Reporting Activities						
8(a) SMD Update incremental rule familiarization and compliance determination	5,627	5,627	0.256	\$19.67	1,441	\$110,683
8(a) SGD incremental rule familiarization and compliance determination	33	33	0.170	\$13.05	6	\$431
Subtotal, Changes to Reporting Activities					1,447	\$111,114
Changes to Reporting Universe						
8(a) SMD Update	5,627	5,500	N/A	N/A	-93,058	-\$7,119,484
8(a) SGD	33	29	N/A	N/A	-445	-\$33,943
Subtotal, Changes to Reporting Universe					-93,503	-\$7,153,427
Net Incremental Change					-92,056	-\$7,042,313

8. ESTIMATING BURDEN AND COST OF THIS COLLECTION

This section of the ICR provides the total burden estimates, changes in the burden estimates from what is currently approved by OMB, and the paperwork burden statement. A detailed description of the information collection activities and related estimates for burden and costs associated with those activities for each respondent category is provided in section 5 of this ICR.

6(a) Total Estimated Respondent Burden and Costs

Table 6-1 presents the bottom-line reporter burden and cost, including average annual and ICR Renewal Period totals under the final rule.

Table 6-1: Annual Average and Overall Incremental Burden and Cost for the ICR Renewal Period

Burden Category	CDR Reporting Cycle Burden				Both CDR Cycle and ICR Renewal Period		ICR Renewal Period (Nov '18 - Nov '21)	
	2016	2017	2018	2019	Annual Average Burden (hours)	Annual Average Cost (2018\$)	Total Burden (hours)	Total Cost (2018\$)
<i>Reporter Burden</i>								

8(a) SMD Update	-91,617	-22,904	-\$1,752,200	-68,712	-\$5,256,600
8(a) SGD	-439	-110	-\$8,378	-330	-\$25,134
Reporter Burden, Total	-92,056	-23,014	-\$1,760,578	-69,042	-\$5,281,734

6(b) Changes in the Estimates

There is an overall annual decrease of 23,014 hours in the total respondent burden that is currently approved by OMB for this ICR. This decrease reflects updates to the definition of small manufacturers and a new definition for small governments. EPA estimates that reporters will experience a net decrease in reporting burden due to the final rule. Table 6 -2 details the reasons for change in annual burden.

Table 6-2: Reasons for Change in Burden

	Changes								Overall ¹
	Section 8(a) SGD Changes to Numbers of Reporters/Chemical Reports - Government		Section 8(a) SMD Changes to Numbers of Reporters/Chemical Reports - Industry		Section 8(a) SGD Government New Reporting Activities		Section 8(a) SMD Industry New Reporting Activities		
	Unit	Total	Unit	Total	Unit ²	Total	Unit ²	Total	
Net Incremental Burden		-111		-23,265	0.043	1	0.064	360	-23,015

General Note:

- All unit and total burden estimates are reported in hours and are on an annual basis.

Footnotes:

¹ The overall net incremental burden in this table does not match the overall net incremental burden presented in Table 6-1 due to rounding.

² These unit burdens are derived by dividing the four-year cycle unit burdens in Table 5 -3 by four.

6(c) PRA Burden Statement

Under the final rule, the incremental reporter burden decrease for this collection of information (identified under EPA ICR No. 1884.13 and OMB Control No. 2070-0162) is estimated to average -4.07 hours per year for the average site.^{8,9} This estimate includes the combined effects of increases to certain reporting activities (incremental rule familiarization and compliance determination) as well as the elimination of reporting for newly exempted chemical reports and/or sites due to the change in the applicable small manufacturer definition.

Burden is defined in [5 CFR 1320.3\(b\)](#), and the activities associated with this collection of information are described in more detail in the information collection request (ICR). Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR Part 9, and are displayed either by publication in

⁸ The number of chemicals per site changes by about -0.05 chemicals per site. The percent partial reports changes by +0.3%. The estimate for percent of sites as new reporters does not change.

⁹ Under the final rule, overall burden for the CDR collection of information is estimated to average 133.05 hours per year for the average multi-chemical submission of 7.45 chemicals per site with 15.71% of reports consisting of partial reports and 15% of sites as new reporters.

the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable.

EPA has established a docket for this ICR that is available for online viewing at <http://www.regulations.gov>. See section 1(b) in this ICR for information about the docket.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing the EPA Docket ID No. EPA-HQ-OPPT-2013-0721 and OMB Control No. 2070-0162, to both EPA and OMB as follows:

- (1) For EPA, submit online using <http://www.regulations.gov>, and
- (2) For OMB, submit via email to oir_submission@omb.eop.gov, addressed to "OMB Desk Officer for EPA."

9. REFERENCES

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10. APPENDICES

Appendix A. Detailed Derivation of Agency Burden and Cost

EPA Staff Activities

EPA activities affected by the rule involve submission receipt and tracking, data review, and quality control. Agency burden is reduced given that these activities are related to the quantity of sites, chemical reports, and CDX registrations, all of which decrease under the rule. The following analysis of Agency burden is limited to incremental change in these variable costs, since fixed costs do not change. Additionally, costs related to EPA activities that involve data use are not included.

Agency personnel are responsible for quality control of data, while contractors perform data processing tasks. Additionally, change in number of CDX registrations is considered to be negligible, and therefore for ease of presentation is not included in estimate of associated Agency cost.

EPA labor costs are based on annual federal wage rates, as presented in Table A -1. As in the ICR renewal (EPA, 2018b), a GS-12 Step 3 is assumed for program staff hours and a GS-13 Step 3 is assumed for information technology (IT) staff hours.

Table A-1: Agency Wage Rate (2018\$)

Labor Category	Data Source for Wage Information	Wage (\$/hour) ¹	Fringe Benefit	Fringes as % Wage	Overhead as % Wage ²	Fringe + Overhead Factor	Loaded Wage (\$/hour)
		(a)	(b)	(c)=(b)/(a)	(d)	(e)=(c)+(d)+1	(f)=(a)*(e)
EPA program staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-12 Step 3 pay rates	\$41.68	Included in 60% overhead	N/A	60%	1.6	\$66.69
EPA IT staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 3 pay rates	\$49.56	Included in 60% overhead	N/A	60%	1.6	\$79.30

Footnotes:
¹ Source: *Salary Table 2018-DCB*. (OPM, 2018).
² The 60% fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (EPA, 2009).

Unit burden and cost associated with EPA staff activities per four-year reporting cycle are the same as in the ICR Renewal (EPA, 2018b) and are presented in Table A -2. The cost associated with quality control of data is performed by program staff and is dependent on the number of chemical reports received.

Table A-2: EPA Staff Burden and Cost of Processing Reports per Four-Year Reporting Cycle

Activity	Unit of Analysis	Agency Burden per Activity (hours)	Agency Cost per Activity (2018\$) ¹
Quality Control of Data for Part I	Per Site	0.0019	\$0.13
Quality Control of Data for Part II	Per Chemical Report	0.0054	\$0.36
Quality Control of Data for Part III	Per Chemical Report	0.0063	\$0.42
Sources include EPA (2015) and EPA (2018b). Footnote: ¹ Based on labor rates (see Table A -1 Error: Reference source not found) for quality control activities and review of e-signatures by program staff GS12 Step 3.			

Contractor Activities

Agency costs also include payment for extramural tasks completed by contractors (this category includes costs to EPA, but not burden hours). Contractor activities affected by the final rule include document receipt, tracking, and data review as presented in Table A -3. These costs are taken from the ICR renewal (EPA, 2018b) and are inflated from 2012 to 2018 dollars with an inflation factor calculated using the Employment Cost Index (ECI), seasonally adjusted, for management, professional, and related occupations in private industry (BLS, 2019b).

Table A-3: Unit Cost of Contractor Activities for Four-Year Reporting Cycle

Activity	Cost 2012\$	Cost ¹ 2018\$
Variable Costs (cost per chemical report)		
Document receipt, tracking, and data review for Part I	\$0.10	\$0.12
Document receipt, tracking, and data review for Part II	\$0.28	\$0.32
Document receipt, tracking, and data review for Part III	\$0.32	\$0.37
Total Cost of Document receipt, tracking, and data review, per single chemical full report	\$0.70	\$0.81
Sources include EPA (2015), EPA (2018b), and BLS (2019b). Footnote: ¹ The inflation rate of 1.15 is calculated as the total compensation Employment Cost Index (ECI) for 2018 divided by the ECI for 2012.		

The final rule will result in net reduction in the reporting universe, which will result in lower Agency burden and cost associated with quality control. Table A -4 presents the estimated incremental Agency burden and cost associated with the rule.

Table A-4: Incremental Agency Burden and Cost of 8(a) SMD Update, Four-Year Cycle

						Incremental Change		
Activity	Staff	Form U Section	Burden per Activity (hours)	Cost per Activity (2018\$)	Unit of Analysis	Affected Universe	Total Burden (hours)	Total Cost (2018\$) ¹
Variable Burden and Cost								
Submission Receipt and Tracking; Data Review	Contractor	Part I	N/A	\$0.12	Sites	-131	N/A	-\$15
		Part II	N/A	\$0.32	Full and Partial Chemical Reports	-1,254	N/A	-\$404
		Part III	N/A	\$0.37	Full Chemical Reports	-1,178	N/A	-\$434
Quality Control	EPA Program Staff	Part I	0.0019	\$0.13	Sites	-131	0	-\$17
		Part II	0.0054	\$0.36	Full and Partial Chemical Reports	-1,254	-7	-\$451
		Part III	0.0063	\$0.42	Full Chemical Reports	-1,178	-7	-\$495
Total Variable Burden and Cost							-14	-\$1,816
General Notes: <ul style="list-style-type: none"> • Results differ slightly from the 8(a) SMD Update EA (EPA, 2019b) due to rounding. • For ease of presentation, change in number of CDX registrations is assumed to be negligible. Footnote: ¹ Based on Labor rates (see Table A -1) for Program Staff GS12 Step 3; for IT Staff GS13, Step 3.								

Appendix B. Estimating Respondent Cost

Wage rates for managerial, technical, and clerical labor are derived and presented in Table B -5. As a simplification and for purposes of ease of presentation, personnel at government-owned reporting sites are assumed to have the same wage rate as the equivalent industry personnel. This section describes the industry wage data used to develop reporting burden estimates.

Standard wage rates for managerial, technical, and clerical levels are developed from information published by the Bureau of Labor Statistics (BLS) and a method outlined in the document *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (Rice, 2002). Average wage data for the three major occupational groups are published quarterly by the BLS in the Employer Costs for Employer Compensation (ECEC) reports (per *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – June 2019* (BLS, 2019a)).

Fringe benefits costs, such as health insurance and vacation for each labor category are taken from the same ECEC series. Following the methodology outlined in Rice (2002), fringe benefits are calculated as a percentage of total wages for each category. An additional 17% is added to the wages in each category to account for overhead, based on information provided by the chemical industry and chemical industry trade associations in the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002). The wages for each of the three categories are then multiplied by benefits and overhead factors to estimate loaded, annual salaries in 2018 dollars. Table B -5 contains the loaded wage rates for the managerial, technical and clerical occupation categories.

Table B-5: Reporter Wage Rates (2018\$)

Labor Category	Data Series ¹	Date	Wage (\$/hour)	Fringe Benefit	Fringes as % Wage	Over-head % Wage ²	Fringe + Overhead Factor ³	Loaded Wage (\$/hour) ⁴
			(a)	(b)	(c) =(b)/(a)	(d)	(e)=(c)+(d)+1	(f)=(a)×(e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-18	\$48.73	\$23.08	47%	17%	1.64	\$79.92
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-18	\$44.35	\$23.43	53%	17%	1.70	\$75.40
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-18	\$20.77	\$10.20	49%	17%	1.66	\$34.48

Footnotes:

¹ *Employer Costs for Employee Compensation Supplementary Tables: December 2006 – June 2019* (BLS, 2019a).

² An overhead rate of 17% is used based on assumptions in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002).

³ The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

⁴ Wage data are rounded to the closest cent in this analysis.

Appendix C. Detailed Response to Comments

The Agency reviewed and considered all comments received on the proposed rule. Copies of all comments are available in the docket for this action (EPA-HQ-OPPT-2018-0321). A discussion of the comments associated with paperwork burden of this rulemaking and the Agency's responses follows.

1. Comment. Two commenters supported the proposed update to the current two-standard definition at 40 CFR 704.3. (Docket IDs: EPA-HQ-OPPT-2018-0321-0089, EPA-HQ-OPPT-2018-0321-0102.)

Response. EPA acknowledges the comment.

2. Comment. Four commenters requested that EPA implement a variable employment-based size standard for CDR and TSCA section 8(a) that uses different industry specific standards defined by NAICS codes, similar to the final rule for Fees for the Administration of the Toxic Substances Control Act (fees rule)(83 FR 52694, October 18, 2018), which is based on the SBA definition for small business, as opposed to the current two-standard revenue-based definition. One commenter further stated that EPA should finalize an employment-based size standard for CDR reporting with the addition of a 100,000 lb volume modifier. Commenters stated that using a definition similar to that in the fees rule would provide consistency and “more accurately reflect the business size of companies in the chemical industry.” Another commenter noted that the EPA’s economic analysis for the proposed rule (Ref. 2) shows that the “SBA Only” definition would provide the least regulatory burden. The same commenter requested to know why a “definition that is variable and maintained by another agency would be unwieldy.” (Comment IDs: EPA-HQ-OPPT-2018-0321-0091, EPA-HQ-OPPT-2018-0321-0096, EPA-HQ-OPPT-2018-0321-0097, EPA-HQ-OPPT-2018-0321-0104.)

Response. Using a variable employment-based size standard similar to the fees rule leads to a reduction of information that would hamper EPA’s ability to carry out the Agency’s obligation under TSCA. As discussed in the proposal, EPA examined the utility of several criteria for “small” including a definition based on SBA’s definition for small businesses. EPA’s decision to finalize the update to the small manufacturer definition as proposed (using 2018\$ rather than 2017\$) is a result of EPA balancing Agency data needs under TSCA section 8(a) for implementing TSCA against the burden imposed on the regulated community. EPA also considered comments on the 2017 determination and the 2019 proposed rule, held multiple meetings with SBA to obtain input, and developed new analyses to understand the impact of the updated definition on the CDR requirements.

The economic analysis for the proposed rule (Ref. 2) evaluated an unmodified SBA-based definition (“SBA Only”) in addition to SBA-based definitions that included production volume modifiers of 100,000 lb, 50,000 lb, and 25,000 lb (SBA+100k, SBA+50k, SBA+25k). The purpose of the production volume modifier was similar to its purpose in the existing definition:

to balance the need to minimize the reporting and recordkeeping burden on small manufacturers with EPA's need for exposure-related information that will be reported under TSCA section 8(a). EPA's analysis found that using SBA standards in isolation results in a large loss of information, approximately 20% of chemical reports and 24% of sites, in addition to those already not reported to CDR as a result of the current definition ("Baseline") (See Ref. 2, Table ES-1). While this option provides the least regulatory burden, it also creates the greatest loss of data to the Agency. EPA determined that losing such a large amount of information would hamper EPA's ability to effectively carry out and implement the requirements of TSCA.

EPA calculated the loss of reports for chemicals on the TSCA Work Plan for Chemical Assessments to be 24% for SBA Only, 8% for SBA+100k, and 3% for the inflation definition. The TSCA Work Plan, originally released in 2012 and updated in 2014, identified a work plan of chemicals for further assessment under TSCA. 2016 amendments to TSCA require that at least 50 percent of all chemical substances undergoing risk evaluation come from the 2014 update to the Work Plan, until the Work Plan chemical list is exhausted. Disproportionate losses of reporting on TSCA Work Plan chemicals constitute a potential loss of information necessary for key Agency decisions. Again, EPA determined that losing an additional 24% or 6% of information on TSCA Work Plan chemicals would hamper EPA's ability to effectively carry out and implement the requirements of TSCA.

Prior to finalizing this final rule, EPA updated its analysis of the reporting impact of the updated small manufacturer definition, as well as the potential reporting impacts of alternative small manufacturer definitions. In the updated analysis, EPA compared the final rule's inflation adjusted small manufacturer definition to the TSCA fees rule's small manufacturer definition with a series of production volume modifiers. The calculated impacts remained largely unchanged from the proposed to final rule. (See the supporting document, Economic Analysis for the Final Rule on the TSCA Section 8(a) Small Manufacturer Definition Update for a more in-depth analysis (Ref. 1)). These impacts of the various alternative small manufacturer definitions were part of the basis for deciding to finalize the updated definition as proposed (updated with 2018\$ rather than 2017\$).

In deciding to finalize the updated definition as proposed (updated with 2018\$ rather than 2017\$), EPA considered the practicality of implementing any potential definition. SBA's variable definition is developed and managed by SBA, and EPA cannot simply cite SBA's definition. As was done with the TSCA fees rule, EPA would need to finalize an SBA-based definition in part or in whole as part of its own regulations. Once done, the two definitions (SBA's and EPA's SBA-based definition) may diverge from one another whenever SBA chooses to update its definition independently of EPA. While EPA adopted parts of the SBA definition for the fees rule, CDR and the fees rule operate differently for small manufacturers. Under the fees rule, small manufacturers pay a reduced fee but are still subject to the same requirements as large manufacturers. Under the CDR rule, however, small manufacturers are completely exempt from reporting. Given that the fees rule reduces burden for small

manufacturers while the CDR rule eliminates burden, EPA does not believe that the fees rule and CDR rule must have identical or comparable small manufacturer definitions.

Additionally, the SBA definition is used to define the largest size a business can be to participate in government contracting programs and compete for contracts reserved or set aside for small businesses. Applications for these programs are reviewed on a case-by-case basis and a determination is made if a business qualifies. For the CDR rule, however, the small manufacturer definition is self-implementing. EPA does not make a determination on whether a company is exempted as a small manufacturer or is required to report to CDR, prior to CDR reporting. For CDR, it is up to the manufacturer to determine if the small manufacturer definition applies. A small manufacturer definition differentiated by NAICS codes could be difficult to apply for reporters because CDR imposes site-based reporting requirements and multiple NAICS codes could apply to a given site. Additionally, EPA believes the current revenue and production volume approach is more amenable to compliance monitoring and believes that it would be more difficult to determine the appropriate NAICS classification for a company because often multiple NAICS apply to a site.

For these reasons, EPA has decided to finalize the updated small manufacturer definition as proposed (updated with 2018\$ rather than 2017\$), instead of finalizing an employee-based size standard.

3. *Comment.* In addition to broadly updating the small manufacturer definition to an employment-based size standard for all manufacturers subject to reporting under TSCA section 8(a), two commenters specifically asked that EPA use the SBA size standard for the utility sector. One commenter went on to state that “EPA should incorporate the SBA size standard of 750 employees as the definition of ‘small manufacturer’ for NAICS 221112, fossil fuel electric power generation; or define ‘total sales’ for NAICS 221112 as only including sale of electricity from coal-fired generation.” (Comment IDs: EPA-HQ-OPPT-2018-0321-0105, EPA-HQ-OPPT-2018-0321-0104.)

Response. EPA is finalizing a standardized two-part revenue-based small manufacturer definition that applies to all chemical substance manufacturers. Given the difficulties that EPA has already described in implementing a small manufacturer standard defined by industry sector, EPA does not believe that the Agency should adopt industry-specific standards. If EPA made specific standards for one industry, it would need to consider additional standards for other industries that requested a standard different from those in the general TSCA section 8(a) small manufacturer definition, which would result in a complex and unworkable definition. That being said, EPA did conduct an analysis of the CDR submitters from utilities sites (government and industry) and also considered the public commenters’ recommendation to use the SBA size standard for NAICS code 221112, fossil fuel electric power generation. From this analysis, EPA found that CDR reporters represent a variety of utilities, one of which is electricity generation. NAICS code 221112 does not have high representation in CDR and is not the most often used electricity NAICS.

EPA disagrees with the concept of relying only on sales associated with a subset of the production of the reportable chemical substance. As described in Unit II.B., the purpose of the small manufacturer exemption is to reduce (or eliminate) the burden of compliance for those entities that have limited financial and personnel resources. Reducing the sales of a company to only a subset of its revenue does not identify the companies that have such limited resources.

4. Comment. One commenter requested that EPA implement a third standard, in addition to the proposed two-part revenue-based standard, for the small manufacturer definition under TSCA section 8(a). The commenter asked that this third standard be an employee-based size standard combined with a production limit, specifically “a small manufacturer definition of 500 or fewer employees, as defined by the U.S. Small Business Administration Office of Advocacy, if annual production (including import) volume of the particular substance does not exceed 100,000 lbs. at any individual site.” (Comment ID: EPA-HQ-OPPT-2018-0321-0102)

Response. EPA disagrees with the comment. Adding a third standard using a different metric than the first two standards would unduly complicate the definition because companies would not only have to identify their company sales volume, but would also have to determine the number of employees. Due to the need to balance the reduction of the reporting and recordkeeping burden on small manufacturers with EPA’s need for exposure-related data, EPA would need to adjust the third standard in such a way that it would not result in additional losses of information. Thus, adding a third standard would introduce additional complexity but without further reducing burden or information received by EPA. See the response to Comment 2 for further discussion.

5. Comment. Two commenters recommended that EPA retain the use of the PPI for Chemicals and Allied Products in future updates of the size standard threshold instead of changing to GDP when determining if an update to the TSCA section 8(a) small manufacturer size standards is warranted. (Comment IDs: EPA-HQ-OPPT-2018-0321-0096, EPA-HQ-OPPT-2018-0321-0102.)

Response. After reviewing the comments received, EPA decided that it will not finalize the change to Gross Domestic Product (GDP) as an inflation index. Instead, EPA will amend the small manufacturer definition at 40 CFR 704.3 to use a five-year average of the PPI for Chemicals and Allied Products when determining if the small manufacturer definition warrants adjustment. EPA proposed the change to GDP because a GDP deflator is less volatile and is broader than the PPI for Chemicals and Allied Products, and therefore EPA believed it to be a better measure when considering an update to the revenue size standards in the proposed definition. While GDP is less volatile, EPA now recognizes that PPI for Chemicals and Allied Products is a better overall accounting of chemical manufacturers that would be subject to reporting under TSCA section 8(a) because it directly reflects the chemical manufacturing sector as opposed to the U.S. economy as a whole. By using a five-year average of PPI for Chemicals and Allied Products, EPA will be able to protect against volatility while continuing to

account for the chemical manufacturers that fall under the small manufacturer definition.

6. Comment. Three commenters requested that EPA change the production volume modifier. Two commenters requested that EPA remove or raise the 100,000 lb production volume modifier used as part of the first standard for TSCA section 8(a) small manufacturer definition. Another commenter asked that EPA evaluate the impacts of decreasing the 100,000 lb production volume modifier. One commenter asked that EPA show “why 100,000 lbs. is an appropriate modifier and consult with the SBA on this threshold.” Additionally, the commenter asked that the Agency “consider a volume modifier with an employee-based standard.” One commenter stated that, with no change in the existing 100,000 lb modifier, the proposed increases of annual company sales thresholds are unlikely to provide regulatory relief from reporting for small scrap metal recyclers. The commenter further stated that while the 100,000 lb limit made sense when inorganic chemical substances were exempt from reporting (before 2003), the threshold has not made sense since inorganic chemical manufacturers became subject to reporting under IUR/CDR because inorganic chemicals are denser than organic chemicals and the production volume threshold is quickly reached. To support their public comments, the commenter provided excerpts from industry testimonies made during the 1975 Senate hearings on pending TSCA legislation. (Comment IDs: EPA-HQ-OPPT-2018-0321-0097, EPA-HQ-OPPT-2018-0321-0100, EPA-HQ-OPPT-2018-0321-0111).

Response. EPA disagrees that the production volume modifier should be changed (either raised or lowered) or that industry-specific modifiers should be developed. EPA has updated the revenue thresholds for the small manufacturer definition based on changes to the value of the U.S. dollar as a result of inflation. There is, however, no corresponding basis for adjusting the production volume modifier. In developing the initial small manufacturer standard, EPA included a production volume modifier to ensure that chemical substances manufactured or imported at high volumes were reported to EPA. The commenters have provided no support to indicate that the 100,000 lb threshold requires updating as a result of changes to the chemical manufacturing sector.

Regarding industry-specific modifiers, such as for the scrap metal industry, EPA believes that it be difficult and resource intensive for EPA to establish, administer, and update industry- or chemical-specific modifiers that align with the 100,000 lb threshold. As stated in EPA’s response to Comment 2, EPA does not feel it is appropriate to have small manufacturer standards that are differentiated by industry. Please see EPA’s full response to Comment 2 for further discussion.

7. Comment. One commenter stated that with respect to the 93 fewer reporting sites, EPA did not show which part of the modified revenue definition applied. The commenter stated that “if all or the majority of the sites are now exempt due to the first standard of \$11 million, the purpose of having a second prong is unclear.” (Comment ID: EPA-HQ-OPPT-2018-0321-0097).

Response. As stated in the economic analysis, the structure of the definition was designed for

effective targeting of small manufacturers (Ref. 1). Note that the information from baseline conditions for this question is unmeasured (i.e., CDR does not receive reports from these manufacturers). Nonetheless, not all sites that are exempted are expected to meet the conditions of the Second Standard of annual sales less than \$12 million. EPA considered the increment of the changes in the proposed rule via the 93 fewer reporting sites (now calculated to be 127 using an updated analysis); EPA found that although a larger portion of sites incur exemption via the Second Standard compared to the First Standard, there is a non-trivial portion of sites that incur exemption via the First Standard (Refs. 3 and 4).

8. Comment. One commenter asked that the updated small manufacturer definition not apply to mercury reporting under CDR. This request was made because the mercury reporting rule promulgated by EPA on June 27, 2018 includes certain exemptions for persons who already report for mercury and mercury-added products to CDR (83 FR 30054). The commenter points out that EPA included this exemption because comparable data would be provided to EPA under the CDR rule. The commenter then states that this assumption may no longer be correct if EPA modifies the small manufacturer standards as proposed.

Response. EPA appreciates the comment. The first reporting cycle for the mercury inventory closed on July 1, 2019. The Agency is currently assessing data received in preparation for the statutory deadline for publishing the mercury inventory not later than April 1, 2020. The Agency is amenable to suggestions of ways to improve the reporting requirements related to mercury supply, use, and trade in the United States, and will take all comments under consideration for future program refinement.

Appendix D. Excerpts from the 2020 CDR Instructions for Reporting

2.2.3 Do You Qualify for a Small Manufacturer or Small Government Exemption? (Question G)

Small manufacturer (the same standard will be used for all manufacturers, except for small governments) (40 CFR 704.3):

- (1) First standard. A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.
- (2) Second standard. A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

For purposes of the definition of a small manufacturer, total annual sales include all sales of the company, not just the total sales of a given chemical substance.

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. States and tribal governments are not considered small governments.

If you have determined that you are a small manufacturer or small government that is manufacturing a CDR reportable chemical substance, evaluate Question H (described in the next section) to determine whether you are exempt from any reporting.

If you do not qualify for a small manufacturer or small government exemption, evaluate Question I in Figure 2-3 (further described in Section Error: Reference source not found) to determine whether you qualify for any other reporting exemptions.

2.2.4. Did You Manufacture a Chemical Substance that is the Subject of Certain TSCA Actions? (Question H)

Small manufacturers and small governments are exempt from CDR requirements unless they manufacture (including import) a chemical substance that is the subject of a rule proposed or promulgated under sections 4, 5(b)(4), or 6 of TSCA, or is the subject of an order in effect under sections 4 or 5(e) of TSCA, or is the subject of relief that has been granted under a civil action under sections 5 or 7 of TSCA (40 CFR 711.9 and TSCA section 8(a)(3)(A)(ii)). The SRS provides information regarding which chemical substances fall into these groups. Table 2 -6 provides examples of how the small manufacturing exemption applies.

Table 2-6. Small Manufacturer or Small Government Exemption (Examples using 2020 CDR Reporting)

Description	Reporting Requirement
Site 1, which is one of several sites owned by Company A, had a production volume of 120,000 lb of Chemical X in 2017. The total annual sales of Company A (all sites combined) were \$7.25 million in 2019.	Site 1 is not required to report for Chemical X because combined sales in 2019 did not exceed \$12 million.
Site 2, which is one of several sites owned by Company B, had a production volume of 90,000 lb of Chemical X in 2016, 75,000 lb in 2017, 82,000 in 2018, and 95,000 in 2019. The total annual sales of Company B (all sites combined) were \$80 million in 2019. None of the other sites produce Chemical X.	Site 2 is not required to report for Chemical X because annual production volume of that chemical substance did not exceed 100,000 lb at any of Company B's sites during 2016-2019, and Company B had total annual sales of less than \$120 million.
Site 3, which is one of several sites owned by Company C, had a production volume of 200,000 lb per year of Chemical X in 2016 through 2019. Site 4, another site owned by Company C, had a production volume of 75,000 lb per year of Chemical X in 2016 through 2019. The total annual sales of Company C (all sites combined) were \$90 million in 2019.	Company C must report for Chemical X at Site 3 because annual production volume at Site 3 exceeded 100,000 lb in at least one year from 2016 to 2019. Company C is not required to report for Chemical X at Site 4 because annual production volume at site 4 did not exceed 100,000 lb and total annual sales was less than \$120 million.
Site 5, which is one of several sites owned by Company D, had a production volume of 50,000 lb of Chemical X in 2018. The total annual sales of Company D (all sites combined) were \$125 million in 2019.	Company D must report for Chemical X at Site 5 because total annual sales in 2019 exceeded \$120 million and the production volume of Chemical X at Site 5 exceeded 25,000 lb in at least one year from 2016 to 2019.
Site 6, which is one of several sites owned by Company E, had a production volume of 120,000 lb of Chemical X in 2016. The total annual sales of Company E (all sites combined) were \$7.25 million in 2019. Chemical X is subject to a section 4 test rule.	Site 6 is required to report for Chemical X. Even though combined sales are less than \$12 million, this chemical substance is subject to a test rule and therefore must be reported.

Description	Reporting Requirement
<p>Site 7, owned by Company F, whose total annual sales is \$90 million in the principal reporting year (2019), manufactures Chemical X, which is the subject of a TSCA section 5(e) consent order and a TSCA section 5(a)(2) SNUR. The annual production volume of Chemical X ranges between 3,000 and 5,000 lb from 2016-2019.</p>	<p>Site 7 is required to report for Chemical X. Based on the sales of less than \$120 million and production volume below 100,000 lb, Company F would qualify as a small manufacturer. Chemical X being the subject of a SNUR does not affect the small manufacturer exemption. However, Chemical S being the subject of a 5(e) consent order does affect the exemption: the small manufacturer exemption does not apply to Company F with respect to its manufacture of Chemical X.</p> <p>Both the SNUR and the 5(e) consent order trigger the reduced reporting threshold of 2,500 lb. Therefore, because Chemical X is subject to a SNUR and a section 5(e) consent order and because Company F has produced Chemical X in amounts above 2,500 lb in at least one year from 2016 to 2019 (in this case all four years), Company F would be required to report.</p>
<p>Site 8 is owned by Company G and manufactured 25,000 lb of Chemical X in 2016 and 20,000 lb in 2017. Chemical X was the subject of a TSCA section 4 test rule promulgated in 2019. Company G's total annual income was the following: \$1 million in 2016, \$2 million in 2017, \$9 million in 2018, and \$12 million in 2019.</p>	<p>Site 8 is required to report for Chemical X. On June 1, 2020, Chemical X is subject to a TSCA section 4 test rule, which means that Company G cannot apply the small manufacturer exemption to its manufacture of this substance.</p> <p>Because annual production volume of Chemical G was 25,000 lb or greater in at least one year from 2016 to 2019 (in this case in 2016), Company G must report for Chemical X.</p>
<p>Site 9 is owned by Company H and manufactures Chemical X. Chemical X has been subject for several years to a TSCA section 4 test rule which sunsets on May 1, 2020. Company H, whose total annual sales were \$9 million in 2019, has manufactured Chemical X in annual amounts above 25,000 lb from 2016-2019. June 1, 2020 was the start of the 2020 submission period.</p>	<p>Company H is not required to report for Chemical X. Although Chemical X was the subject of a TSCA section 4 test rule (which could have eliminated the ability to apply the small manufacturer exemption to manufacture of Chemical X), June 1, 2020 is after the sunset date. As of June 1, 2020, Chemical X is no longer the subject of a TSCA section 4 test rule. Therefore, Company H, with total annual sales less than \$12 million in 2019, would be eligible to apply the small manufacturer exemption to its manufacture of Chemical X.</p>
<p>Municipal utility 1 is owned by a US city containing a population of 39,250. This utility produces 57,000 lb of Chemical X in 2016 and approximately the same amount in years 2017 through 2019.</p>	<p>Municipal utility 1 is not required to report under CDR, because it is owned by a US city with a population that does not exceed 50,000, and therefore qualifies for the small government exemption.</p>

Description	Reporting Requirement
<p>Public utility district 1 is owned by a US county containing three separate townships, in 2016, one containing a population of 8,300, the second containing a population of 33,600, and the third containing 10,850. The county had a total population of 52,750 in 2016. The population fluctuates in each township through 2019, but does not drop below 50,000 total in any single year.</p>	<p>Public utility district 1 is required to report for any chemicals meeting the reporting requirements. Based on its 2019 population, it does not qualify for the small government exemption as its population is greater than 50,000.</p>
<p>Public utility district 2 is owned by a US county containing three separate townships, in 2016 and 2017, one containing a population of 26,550, the second containing a population of 6,400, and the third containing 12,700 (total of 45,650 for the county). In 2018, a fourth township containing a population of 8,900 is added to the county, raising the total population that the utility district services to 54,550. The population fluctuates in each township through 2019, but does not drop below 50,000 total.</p>	<p>Public utility district 2 is required to report for any chemicals meeting the reporting requirements. Although it would have qualified for the small government exemption in 2016 and 2017, its population grew and exceeded the 50,000 population threshold for 2019, the principal reporting year. The public utility is required to consider reporting based on the annual production volume during each years of the reporting cycle (2016-2019).</p>